

REMARKS

Claims 1-61 were pending. Applicant hereby cancels claims 6 and 30-61 and explicitly reserves the right to pursue the subject matter of the cancelled claims in one or more subsequent related applications. New claims 62 and 63 have been added. Support for claim 62 can be found in the specification as filed at page 59, line 20. Support for claim 63 can be found in the specification as filed at page 26, line 8. Claims 1, 2, 4, 5, 7, 9, and 15 have been amended to more particularly point out the subject matter of the claimed invention. Support for the amendments can be found throughout the specification as filed. In particular, support for the amendment to claim 1 and 7 can be found in the specification as filed at page 61, lines 19-21. Additional support for the amendment to claim 1 can be found in the specification as filed at page 1, line 8, page 17, line 20 through page 18, line 2, page 8, line 19, page 64, lines 21-22, page 65, lines 12-14, and page 8, line 22 through page 9, line 3. Support for the amendment to claim 2 can be found in the specification as filed at page 60, lines 17-21. Support for the amendment to claim 4 can be found in the specification as filed at page 61, lines 11-14. Support for the amendment to claim 5 can be found in the specification as filed at page 61, lines 16-18. Support for the amendment to claim 9 can be found in the specification as filed at page 19, lines 11-13. Support for the amendment to claim 15 can be found in the specification as filed at page 20, lines 12-13. No new matter has been added.

THE INDEFINITENESS REJECTION SHOULD BE WITHDRAWN

Claims 1-29 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicant respectfully disagrees.

According to applicable case law, 35 U.S.C. § 112, second paragraph, requires a claim to have a clear and definite meaning when construed in light of the complete patent document. See *Standard Oil v. American Cyanamide Co.*, 227 USPQ 293 (Fed. Cir. 1985). In particular, definiteness turns on whether one of skill in the relevant art would understand the bounds of a claim when read in light of the specification. See *Orthokinetic Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986).

In the instant case, the Examiner articulates six separate grounds for why the above recited claims are indefinite and thus allegedly fail to apprise the skilled artisan of their apparent scope. The Applicant addresses each of these six grounds in turn below.

First, the Examiner asserts that claim 1, as written, and consequently dependent claims 2-29, are indefinite and incomplete. Specifically, the Examiner points out that claim 1 fails to recite a step whereby an antibody is expressed. January 30, 2003 Office Action at 3. Applicant has amended claim 1 so as to more particularly point out the claimed invention. Specifically, Applicant has added a step whereby the nucleotide sequence encoding the immunoglobulin polypeptide is expressed. Applicant submits that the Examiner's indefiniteness rejection is thereby rendered moot.

Second, the Examiner states that claim 4 is vague. In particular, the Examiner alleges that the term "suitable" as used in claim 4 is indefinite because it implies a latent property and the conditions for the latent property must be clearly defined. Applicant has amended claim 4 to delete reference to the term "suitable." Applicant respectfully asserts that the amendment to claim 4 obviates the Examiner's rejection.

Third, the Examiner alleges that claim 5 is unclear. Specifically, the Examiner takes issue with the recitation of the phrase "derived from". Applicant has amended the claim to more particularly point out the claimed invention. Specifically, Applicant has amended claim 5 to delete reference to the phrase "derived from." Applicant respectfully asserts that the claim as amended is definite and therefore that the amendment obviates the Examiner's indefiniteness rejection.

Fourth, the Examiner purports that "a combination thereof" as used in claim 9 is unclear because the metes and bounds of the phrase are not clearly defined. Applicant has amended claim 9 to more particularly point out that which the Applicant regards as the invention. Specifically, the phrase "a combination thereof" has been deleted. Applicant respectfully asserts that the claim as amended is definite and the Examiner's rejection is thereby rendered moot.

Fifth, the Examiner alleges that claim 15 is vague, as the metes and bounds of the term "operable" are not clearly defined. Applicant has amended the claim to more

particularly point out the claimed invention. Specifically, Applicant has amended the claim to recite the limitation that the promoter “directs expression” in oviduct cells. Applicant respectfully asserts that the claim as amended is definite and the Examiner’s rejection is obviated.

Finally, the Examiner contends that claim 29 is incomplete. The Applicant respectfully points out that this rejection is duplicative of the Examiner’s first indefiniteness rejection. Accordingly, the amendment to claim 1 discussed above, upon which claim 29 depends, obviates the Examiner’s rejection.

THE LEGAL STANDARD FOR ANTICIPATION

The legal standard for anticipation is one of strict identity. For a claim to be anticipated, a single prior art reference must disclose each and every limitation of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1985) (“It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention.”). In other words, there must be no difference between the claimed invention and the reference as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Fdn. v. Genetech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991).

Further, a prior art reference must be an *enabling* reference to anticipate. See *Akzo N.V. v. U.S. Int’l Trade Comm’n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986) (“the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.”). *See also* MPEP § 2121.01; *In re Hoeksema*, 399 F.2d 269 (CCPA 1968) (“In determining that quantum of prior art disclosure which is necessary to declare an applicant’s invention ‘not novel’ or ‘anticipated’ within section 102, the stated test is whether a reference contains an ‘enabling disclosure’”).

THE ANTICIPATION REJECTION OVER MOHAMMED SHOULD BE WITHDRAWN

Claims 1, 2, 4, 5, 9, and 19-29 are rejected as anticipated by Mohammed *et al.*, *Immunotechnology* 4:115-125 (1998) (“Mohammed”). Applicant has amended the claims and respectfully asserts that the amended claims are novel over Mohammed.

Applicant submits that Mohammed does not teach every element of the presently claimed invention. Mohammed describes antibodies produced in chicken B lymphoblastoid “DT-40” cells. Mohammed at Section 2.1, p. 117. Mohammed does not teach the production of antibodies in any cells other than chicken B lymphoblastoid cells. Since the claims currently recite production of an antibody by an avian cell that is a fibroblast, oviduct, embryonic, germ-line, ovum, or testicular cell, Mohammed does not teach every element of the claims.

Applicant further notes that Mohammed also does not render the claimed invention obvious. While Mohammed teaches expression of antibodies in antibody-expressing cells, *i.e.*, B lymphoblastoid cells, it does not suggest expression of antibodies in non-antibody-producing cells.

In sum, Mohammed does not teach all the limitations set forth in the claims and therefore cannot anticipate the instant claims. Accordingly, in view of the foregoing, Applicant submits that the rejection is in error, and respectfully requests its withdrawal.

THE ANTICIPATION REJECTION OVER DITULLIO
SHOULD BE WITHDRAWN

Claims 1, 2, 4-9, 11, 12, 14-17, and 20-29 are rejected under 35 U.S.C. § 102(e) as being anticipated by WO 00/75300 A2 by Ditullio *et al* (“Ditullio”). Applicant respectfully submits that Ditullio is not a proper 102(e) reference. Ditullio is a WIPO publication of an International Application filed June 2, 2000. Since Ditullio’s international filing date is prior to November 29, 2000, it is not a proper 102(e) reference. See MPEP 706.02(f)(1).

Even assuming *arguendo* that Ditullio is a proper 35 U.S.C. § 102 reference, Ditullio does not anticipate because Ditullio does not contain an enabling disclosure. More specifically, Ditullio does not enable a method of producing antibodies. Although aspiring to antibody production in transgenic chicken cells, at most Ditullio demonstrates the introduction of a vector containing the human insulin gene into certain tissues of the chicken by injection of the blastoderm of hard-shell eggs. No expression of insulin protein, much less expression of a multi-chain antibody, is reported. Accordingly, Ditullio only enables the introduction of nucleic acids comprising a transgene encoding a single polypeptide into a

chicken cell. In contrast, claim 1 is directed to a method for the production of an antibody in an avian cell.

Thus, Ditullio does not anticipate the claimed invention. By virtue of their dependencies, claims 2, 4-9, 11, 12, 14-17, and 20-29 incorporate the limitations of claim 1 and therefore are not anticipated by Ditullio.

THE LEGAL STANDARD FOR OBVIOUSNESS

To find obviousness, there must be a reason or suggestion in the art for carrying out the invention, other than the knowledge learned from the Applicant's disclosure. *In re Dow Chemical Co.*, 837 F.2d 439, 473 (Fed. Cir. 1988). Consequently, a finding of obviousness under 35 U.S.C. section 103 requires a determination of (1) the scope of and content of the prior art; (2) the level of ordinary skill in the art; (3) the difference between the claimed subject matter and the prior art; and (4) whether the differences are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383 U.S. 1 (1966).

The Federal Circuit has articulated that the prior art must either expressly disclose every limitation or suggest modifications to meet every claim limitation. *Litton Indus. Products, Inc. v. Solid State Systems*, 755 F.2d 158, 164 (Fed. Cir. 1985); see also MPEP 2143.03 (8th edition, revised February 2003). Prior art references may thus be combined to render an alleged invention obvious under 35 U.S.C. § 103, however, the teachings of the references can be combined only if there is some suggestion or incentive to do so. *ACS Hospital Systems Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1575 (Fed. Cir. 1984).

The Federal Circuit has indicated that a *prima facie* case of obviousness requires "objective evidence of record" demonstrating that there is prior art that teaches or suggests combining the asserted references as proposed. *In re Lee*, 277 F.23d 1338, 1341 (Fed. Cir. 2002). The Court has also made clear that the requirement of a showing of the teaching or motivation to combine prior art references must be "clear and particular." Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence." *In re Dembicza*k, 173 F.3d 944, 999 (Fed. Cir. 1999). Furthermore, the

motivation to combine references may originate from one of three sources: the nature of the problem to be solved, the teachings of the prior art, or the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

Moreover care must be exercised not to use the Applicant's disclosure to fill in the gaps in the prior art. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re Grabiak*, 769 F.2d 729 (Fed. Cir. 1985). Thus, Applicant's own teaching in the application in question also cannot constitute a proper basis for formulating obviousness rejections; hindsight reconstruction on the basis of an applicant's disclosure is impermissible. *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995); *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995).

THE OBVIOUSNESS REJECTION SHOULD BE WITHDRAWN

Claims 1, 3, 10 and 13 are rejected under 35 U.S.C. § 103(a) as being obvious over Ditullio when taken with Michael *et al.* (U.S. Pat. No. 6,143,559, published November 7, 2000) ("Michael"). Applicant respectfully disagrees.

As discussed above, Ditullio teaches the introduction of insulin coding DNA into cells of a chicken and is not enabling for antibody production. Michael discloses producing chicken monoclonal antibodies, cloning the DNA encoding these chicken antibodies and then expressing the chicken antibodies in cultured mammalian cells, not chicken cells. There is no teaching to express the antibodies in cultured chicken cells. One of ordinary skill in the art would find no clear and particular motivation to combine the two references since Ditullio teaches polypeptide expression in chicken cells while Michael teaches chicken antibody expression in mammalian cells only.

Even assuming, *arguendo*, there were a motivation to combine, Michael does not cure the defects of Ditullio. Ditullio relates to attempting to produce proteins in transgenic chickens while Michael in no way relates to producing any type of transgenic animal. Rather Michael teaches recombinant expression in mammalian cell culture. This teaching, in combination with that of Ditullio, does not result in the claimed invention.

Thus, Applicant asserts that the claimed invention is not obvious in light of Ditullio when taken with Michael.

CONCLUSION

The Applicant respectfully requests that the remarks of the present response be entered and made of record in the instant application. Claims 1-5 and 7-29 fully meet all the statutory requirements for patentability. Withdrawal of the Examiner's rejections and early allowance and action for issuance are respectfully requested.

Respectfully submitted,

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Enclosure